

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

In re Entresto (Sacubitril/Valsartan) Patent Litigation

C.A. No. 20-2930-RGA

NOVARTIS PHARMACEUTICALS
CORPORATION,

Plaintiff,

V.

ALKEM LABORATORIES LTD.,
AUROBINDO PHARMA USA INC.,
AUROBINDO PHARMA LTD.,
CRYSTAL PHARMACEUTICAL
(SUZHOU) CO., LTD., TORRENT
PHARMA INC., TORRENT
PHARMACEUTICALS LTD.,

Defendants.

PUBLIC VERSION FILED: November 28, 2022

C.A. No. 19-1979-RGA

NOVARTIS PHARMACEUTICALS
CORPORATION,

WHEREAS, Alkem stipulates and acknowledges that [REDACTED] of United States Patent No. 8,101,659 (“the ’659 Patent”), [REDACTED] of United States Patent No. 8,796,331 (“the ’331 Patent”), [REDACTED] of United States Patent No. 11,096,918 (“the ’918 Patent”), and [REDACTED] of United States Patent No. 11,058,667 (“the ’667 Patent”) (collectively, the “Patents-In-Suit” and the “Asserted Claims of the Patents-In-Suit”), asserted in these actions against Alkem, are valid and enforceable;

WHEREAS, Novartis and Alkem stipulate that the Settlement Agreement supersedes the March 16, 2022, Order in Civil Action Nos. 20-2930-RGA and 19-1979-RGA, wherein Alkem stipulated to infringement of the ’659 and ’331 Patents;

WHEREAS, Novartis and Alkem stipulate that the Settlement Agreement supersedes the July 20, 2022, Order in Civil Action Nos. 20-2930-RGA, 19-1979-RGA, 21-1330-RGA, and 22-32-RGA, wherein Alkem stipulated to infringement of [REDACTED] of the ’659 Patent, [REDACTED] of the ’331 Patent, [REDACTED] of the ’918 Patent, and [REDACTED] of the ’667 Patent;

WHEREAS, Alkem stipulates and acknowledges that Alkem’s filing of ANDA No. 213764, including any amendments or supplements thereto, infringes all Asserted Claims of the Patents-In-Suit under 35 U.S.C. § 271(e)(2);

WHEREAS, Alkem stipulates and acknowledges that the use, sale, offer for sale, manufacture, and/or importation of the products that are the subject of Alkem’s Abbreviated New Drug Application No. 213764 infringe all Asserted Claims of the Patents-In-Suit under 35 U.S.C. § 271(a) (including during any extension of patent term for the ’659 Patent pursuant to 35 U.S.C. § 156), and Alkem will induce and contribute to such infringement of all Asserted Claims of the ’331 and ’667 Patents under 35 U.S.C. §§ 271(b) and (c); and

WHEREAS, Novartis has provided Alkem with a covenant not to sue on United States Patent Nos. 8,877,938 (“the ’938 Patent”) and 9,388,134 (“the ’134 Patent”) and Novartis’s claims against Alkem and Alkem’s Counterclaims against Novartis with respect to the ’938 and ’134 Patents have been dismissed without prejudice by Order in Civil Action Nos. 20-2930-RGA and 19-1979-RGA signed December 6, 2021.

IT IS HEREBY ORDERED, DECREED, AND ADJUDGED:

1. Judgment is entered that all Asserted Claims of the Patents-In-Suit are valid and enforceable.
2. Judgment is entered that Alkem’s filing of ANDA No. 213764, including any amendments or supplements thereto, infringes all Asserted Claims of the Patents-In-Suit under 35 U.S.C. § 271(e)(2).
3. Judgment is entered that the use, sale, offer for sale, manufacture, and/or importation of the products that are the subject of Alkem’s Abbreviated New Drug Application No. 213764 infringe all Asserted Claims of the Patents-In-Suit under 35 U.S.C. § 271(a) (including during any extension of patent term for the ’659 Patent pursuant to 35 U.S.C. § 156), and Alkem will induce and contribute to such infringement of all Asserted Claims of the ’331 and ’667 Patents under 35 U.S.C. §§ 271(b) and (c).
4. By virtue of the license granted by Novartis to Alkem as part of the Settlement Agreement, judgment is entered that there no longer exists a cause of action for infringement of the Patents-In-Suit by the products that are the subject of Alkem’s Abbreviated New Drug Application No. 213764.
5. This Consent Judgment constitutes a “consent decree” pursuant to 21 U.S.C. § 355(j)(5)(B)(iii)(I)(bb), such that Final Approval of Alkem’s Abbreviated New Drug

Application No. 213764 under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) may be granted on the date that this Consent Judgment is entered.

6. Pursuant to the terms of the Settlement Agreement, all other Novartis claims are dismissed without prejudice and all of Alkem's defenses, demands and counterclaims are dismissed with prejudice.
7. This Court retains jurisdiction over all disputes arising out of the Settlement Agreement.
8. Alkem, and each of its affiliates, is hereby enjoined from directly or indirectly passing title or delivering to customers in the United States the products that are the subject of Alkem's Abbreviated New Drug Application No. 213764 prior to the Generic Entry Date, as set forth in the Settlement Agreement, subject to the exceptions provided in the Settlement Agreement.
9. The injunction described in the foregoing paragraph shall take effect immediately upon entry of this Order by the Court.
10. During the term of the injunction, the Court retains jurisdiction over this action, including implementation of, or disputes arising out of, this Order of Injunction.
11. Each party shall each bear its and their own costs and attorney fees.
12. Novartis and Alkem each expressly waive any right to appeal or otherwise move for relief from this Consent Judgment and Order of Injunction.
13. Nothing herein shall prevent the U.S. Food & Drug Administration from granting final approval to Alkem's ANDA No. 213764.

United States District Judge